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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

AFREMOVA, VERA

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                              |
|------------------------------|--------------------------------------|------------------------------|
| <b>Office Action Summary</b> | Application No.<br><b>09/484,048</b> | Applicant(s)<br><b>Steen</b> |
|                              | Examiner<br><b>Vera Afremova</b>     | Art Unit<br><b>1651</b>      |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on Dec 3, 2002
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above, claim(s) 2-4 and 8-23 is/are withdrawn from consideration.
- 5)  Claim(s) 5, 7, 24-32, and 34 is/are allowed.
- 6)  Claim(s) 1 and 33 is/are rejected.
- 7)  Claim(s) 6 is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. 09/093,614.
  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

### *Status of claims*

Claims 1, 5-7, 24-34 as amended [Paper No. 22 filed 12/03/2002] are under examination in the instant office action.

Claims 2-4, 8-23 were withdrawn from consideration as being drawn to non-elected inventions. Applicant elected without traverse the invention of original claims 1 and 5-7. [Paper No. 7 filed 1/25/2001].

### *Response to Arguments*

Applicant's arguments filed 12/03/2002 [Paper No. 22] have been fully considered but they are not all found persuasive for the reasons below.

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 33 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wlakenbach et al. [IDS-12-AO, 1991] taken with Ingemansson *et al.* [IDS-12-AN, 1995], Ingemansson *et al.* [IDS-1, AT-2, 1995], Pinsky *et al.* [IDS-1, AQ-2, 1994] and Naka *et al.* [IDS-1, AT-1, 1995].

Claim 1 is directed to a preservation solution comprising calcium ion, colloidosmotically active substance and nitroglycerin. Claim 33 is further drawn to a method for preserving organs

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or tissues by storing the organs or tissues in the claimed solution for 36 hours and more at 0.5-12°C and/or for more than 36 hours at 0.5-12°C.

The cited references are relied upon as explained in the prior office action and repeated herein.

The cited references by Wlakenbach et al. [IDS-12, AO, 1991], Ingemansson *et al.* [IDS-12, AN, 1995] and Ingemansson *et al.* [IDS-1, AT-2, 1995] teach a preservation solution comprising various preservation solution components including calcium ion and colloidosmotically active substance. They also teach methods for preserving organs or tissues by storing the organs or tissues in the preservation solution under conditions as presently claimed.

For example: Wlakenbach et al teaches a preservation solution which comprises calcium, about 1-15% of dextran 40, buffer, glucose and ions of potassium, magnesium and sodium. The reference also teaches a method for preserving organs or tissues such as cornea, for example, by storing them in the preservation solution at low temperature including 4°C or between 0.5 and 12°C for a period of time such as about 7 days including time periods such as more than 36 hours and less than 36 hours. The cited references by Ingemansson *et al.* [IDS-12, AN, 1995] and Ingemansson *et al.* [IDS-1, AT-2, 1995] teach the use of various solutions in the methods for preservation of various organs and tissues of animals including tissues with blood vessels, veins, vascular endothelium and/or contractile tissues wherein solutions comprise calcium, colloidosmotically active substance or dextran, glucose, buffer and ions of potassium, magnesium and sodium at various concentrations. The reference by Ingemansson *et al.* [IDS-1,

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AT-2, 1995] teaches that Perfadex solution comprising colloidosmotically active substance manifests superior effects related to preservation of contractile tissues. The reference by Ingemansson *et al.* [IDS-12, AN, 1995] teaches that incorporation of calcium ion into storage or organ-bath solutions resulted in preservation of a contractile capacity of animal tissues for a period of time more than 36 hours and it suggests incorporation of calcium into various preservation solutions including Perfadex, for example (page 1181, col. 1, par. 3).

The cited references by Wlakenbach *et al.* [IDS-12, AO, 1991], Ingemansson *et al.* [IDS-12, AN, 1995] and Ingemansson *et al.* [IDS-1, AT-2, 1995] lacking teaching drawn to the inclusion of nitroglycerin into solutions in the method for preservation of animal organs and tissues.

However, the references by Pinsky *et al* and by Naka *et al* teach that incorporation of nitroglycerin in storage or preservation solution enhances survival of animal tissue or organ grafts (see abstracts), that nitroglycerin maintains vascular homeostasis in animal organs and tissues and that nitroglycerin is added to solutions intended for both perfusion and preservation including Ringer's solution which contains calcium. The suggested amounts of nitroglycerin are about 0.1 mg/ml.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to include nitroglycerine in storage or preservation solutions as taught by Pinsky *et al.* and Naka *et al* with a reasonable expectation of success and with the expected benefit if maximizing the preservation of animal organs and tissue useful, for example,

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for transplantation because the prior art teaches that incorporation of nitroglycerin into storage solutions including preservation solutions with calcium enhances survival of animal tissue or organ grafts and that nitroglycerin maintains vascular homeostasis in animal organs or integrity of animal tissues. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

With regard to the cited references applicant appears to argue that they teach the use of solutions with particular ingredients intended <sup>for</sup> preserving particular organs or tissues (pages 4-6). Yet, the solution and method of claims 1 and 33 are generic and not limited to particular ingredients and/or preservation of particular organs or tissues. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When applicant claims a "composition in terms of function . . . and the composition of the prior art is substantially similar as that of the claim but the function is not explicitly disclosed by the reference, the rejection is proper. (MPEP 2112).

Applicant further argues the synergistic effect of calcium and nitroglycerin (response page 6-8). However, the prior art suggests this combination as adequately demonstrated by the references by Pinsky *et al.* and Naka *et al.*. The evidence necessary to overcome a *prima facie* case of obviousness must not only be clear and convincing, but must also be commensurate in scope with the claimed subject matter. For example: the solutions of claims 1 and 33 require a

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combination of both calcium and nitroglycerin but the claimed solutions are not limited to particular amounts of calcium and nitroglycerin which produce synergistic effects as argued. Moreover, the solutions of claim 1 and 33 are not limited to the any ingredients which are commonly used in the preservation solutions and which are reasonably expected for a successful preservation of animal tissue and organ preservation. Claim 1 is broad and it is not limited to any particular colloidosmotically active substance which could be water, for example. The particular applicant's showing (Fig. 1), which is argued as a support for synergistic effect of calcium-nitroglycerin combination, demonstrates animal tissue contractile capacity and encompasses the use of the solution Perfadex which contains dextran 40 as colloidosmotically active substances. Moreover, the amounts of calcium and nitroglycerin used in Fig. 1 do not delineate clearly the amounts of calcium and nitroglycerin required to obtain the touted synergistic result.

Thus, the applicant's showing and arguments do not commensurate in scope with the claimed subject matter. The allegation that limited data is sufficient to establish the existence of synergism from other such ingredients is without merit. It is well recognized that synergism is a highly unpredictable result which is very dependent on the ingredients used and the amounts of each. Thus any combination for which synergism is not clearly established would be properly rejected because non-obviousness would not have been established.

Claims 1 and 33 are not allowed.

Claims 5, 7, 24-32 and 34 as presently amended are free from prior art and allowable.

Claim 6 is free from prior art but is objected as being dependent on the rejected claim 1.

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***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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February 12, 2003.



SANDRA E. SAUCIER  
PRIMARY EXAMINER